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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,208	02/08/2002	Patrick Bernardelli	A0000135-01-CFP	8057
7590 Claude F Purchase Jr Warner Lambert Company 2800 Plymouth Road Ann Arbor, MI 48105			EXAMINER HABTE, KAHSAI	
			ART UNIT 1624	PAPER NUMBER

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

**Application No.**

10/049,208

**Applicant(s)**

BERARDELLI, PATRICK

**Examiner**

Kahsay Habte, Ph. D.

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 18-37 are pending.

#### ***Response to Amendment***

2. Applicant's amendment filed 3/26/2004 in response to the previous Office Action (11/26/2003) is acknowledged. Rejections of claims 18-37 under 35 U.S.C. § 112, first and second paragraph (paragraphs 3 and 4a-4b) have been obviated. The rejection in item 4c has been maintained. Even though applicants overcome most of the rejection the amendment introduces new issues.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

- a. Claim 18 and claims dependent thereon are rejected because the term "analyzing" is not clear. Claim 18 is drawn to a process claim not to a method of analyzing potential metabolites. There is no analysis step. <sup>Also,</sup> What is analyzed?  
^  
Structure? Biological activity? Safety? Purity? It is recommended that applicants delete this term from the claim to overcome the rejection.

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b. In claim 18, the phrase "drug candidate" is indefinite. What are covered and what are not? How can one tell if a compound is a drug candidate or not? What are the criteria? Is anything not a candidate?

c. Claim 19 recites the limitation "further comprises a polyhalogenated aliphatic solvent" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no mention of "polyhalogenated aliphatic solvent" back in claim 18. Claim 18 recites "an inert aromatic solvent" that is narrower in scope compared to original claim 1. Original claim 1 recites the broader term "inert aprotic solvent selected from a polyhalogenated aliphatic or aromatic solvent", but new claim 18 does not recite said broader term.

### ***Response to arguments***

Applicant's argument filed 03/26/2004 has been fully considered but it is not persuasive.

Applicants argue that claim 19 requires both an inert aromatic solvent and polyhalogenated aliphatic solvent, but the examiner disagrees with applicants. Claim 18 recites only inert aromatic solvent, but not inert aromatic solvent and polyhalogenated aliphatic solvent. Aromatic solvent indicates that the presence of an aromatic group such as phenyl. This is different from aliphatic solvent (no ring). Note that the proviso "the inert aprotic solvent is not dichloromethane, dichloroethane or trichloroethane" in the original claim 1 was put to exclude a prior art. Applicants have take out the proviso

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and also taken out the phrase "polyhalogenated aliphatic" from claim 18. In claim 19, the phrase "polyhalogenated aliphatic solvent" still lacks antecedent basis, since there is no mention of any polyhalogenated aliphatic solvents back in claim 18.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### ***Conclusion***

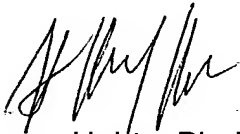
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

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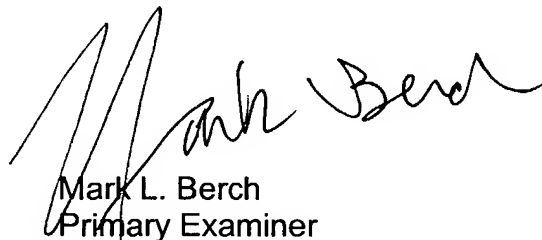
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.  
Examiner  
Art Unit 1624



Mark L. Berch  
Primary Examiner  
Art Unit 1624

KH

April 8, 2004